



U.S. SMALL BUSINESS ADMINISTRATION
WASHINGTON, DC 20416

OFFICE OF THE CHIEF COUNSEL FOR ADVOCACY

AUG 10 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Concept Paper: Drug Products That Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness.

Dear Sir/Madam:

For reasons stated below, the Office of Advocacy respectfully requests that the comment deadline for the above-referenced FDA Concept Paper be extended by at least 90 days from the time all documents contained in the bibliography and referenced in the Concept Paper have been placed in the docket.

The Office of Advocacy of the U.S. Small Business Administration (SBA) was established by Congress pursuant to Pub. L. No. 94-305 to represent the views of small business before federal agencies and Congress. One of the primary functions of the office is to measure the costs and other effects of government regulation on small businesses and make proposals for eliminating excessive or unnecessary regulations of small businesses. The Chief Counsel of Advocacy is required by section 612(a) of the Regulatory Flexibility Act (RFA)¹ to monitor agency compliance with the RFA and to report annually to Congress and the President on such compliance. The Chief Counsel of Advocacy is also authorized to appear as *amicus curiae* in any action brought in court to review a rule. In any such action, the Chief Counsel is authorized to present views with respect to compliance with the RFA, the adequacy of the rulemaking record with respect to small entities, and the effect of the rule on small entities.²

Industry groups that will be affected by the recommendations stemming from this Concept Paper have expressed concern that the present 45-day comment period (which expires August 15, 2000) is insufficient to evaluate the impact of the document. The 45-day period is particularly inadequate since many of the research studies and other documents referenced in the Concept Paper have not been placed in the docket, and therefore, are not available for public inspection or comment. The Office of Advocacy is advancing this request by the industry because pharmacies that compound drug products are primarily small businesses, and because the policies adopted as a result of the Concept Paper will have broad and serious implications for these small businesses.

¹ 5 U.S.C. § 601 et seq. as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857.

² *Id.* at § 612

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Without a doubt, the Concept Paper will serve as the basis of future regulations that will severely curtail the ability of compounding pharmacists to compound and sell certain drug products. Specifically, FDA is attempting to identify, list and define drug products that present "demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product." FDA wants to include both specific drug products and categories of products that are grouped by relevant factors (e.g., specific drug delivery system) in the list of drug products that are demonstrably difficult to compound. Among the products FDA wants to include in their definition of "demonstrably difficult" are sterile products, products with transdermal delivery systems (skin patches), metered dose inhaler products, and dry powder inhaler products. The data and research supporting FDA's recommendations on the referenced products have not been made available for public comment.

There is well-established case law that points to the importance and necessity of a complete administrative record on which the interested public can comment.³ Courts have ruled that when agencies fail to place a large percentage of their supporting evidence on file, they have acted in an arbitrary and capricious manner.⁴

The Office of Advocacy also has concerns about the level of outreach used by the agency to apprise the industry and interested persons about the Concept Paper and the agency's request for comments. The Concept Paper was published on FDA's website rather than in the *Federal Register*. While publication on FDA's website is one form of outreach, it may limit the number of comments submitted because some concerned entities are accustomed to searching the *Federal Register* for significant policy and regulatory actions. Moreover, FDA's outreach efforts may be subject to the judicial review provisions of the RFA once a rule is promulgated.⁵ In light of the scope, importance and controversy surrounding the issues contained in the Concept Paper, FDA should have initiated a broader outreach effort.

Given that there are serious issues about the incomplete docket, the potential impact on the industry and the limited outreach, the Office of Advocacy requests that a 90-day comment period be allowed to give the industry adequate time to prepare meaningful comments. The 90-day period should begin only after all supporting documentation has been added to the docket. Thank you for your consideration of this important matter.

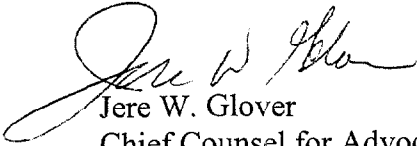
³ See, e.g., *Connecticut Light & Power Co. v. Nuclear Regulatory Commission*, 673 F.2d 525, 530 (D.C. Cir. 1982) ("the purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency. ... In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary").

⁴ See, *Hanover Potato Products, Inc. v. Sullivan*, No. 1:CV-90-0746, slip op. at 4-5 (June 21, 1990), quoted in *Hanover Potato Products, Inc. v. Sullivan*, No. 90-5738, 1991 U.S. App. LEXIS 4423 (3rd Cir. App. March 20, 1991).

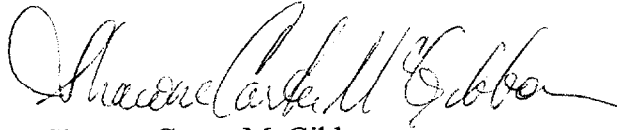
⁵ See 5 U.S.C. §§ 609(a) and 611.

Please do not hesitate to contact our office if you have any questions, 202-205-6533 or 202-205-6945.

Sincerely,



Jere W. Glover
Chief Counsel for Advocacy



Shawne Carter McGibbon
Asst. Chief Counsel for Advocacy